सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2021/000155

1. M/s Modern Orthodontics, 2024, Gobind Nagar, Circuit House Road, Ludhiana, Ludhiana, Punjab (India) - 141001 Telephone No.: 7738993291 FAX: 01612412312 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Modern Orthodontic, Hambran Industrial Area, Mullanpur Road, Village Hambran, , Ludhiana, Punjab (India) - 141110 Telephone No.: 7738993291 FAX: 01612412312
2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Orthodontic Bracket- Stainless Steel Model No.:NIL Intended Use:Orthodontic Brackets are known as dental braces in layman language. These are used for the purpose of straightening of crooked teeth. These are placed on the teeth and then they act as means of transferring forces of orthodontic wires to teeth. Once the treatment with braces is over, these are removed from the teeth and discarded Class of medical device:Class B Material of construction:Stainless Steel 17-4 PH, Stainless Steel 316 L , Stainless steel 305. All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades. Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

2	Generic Name:Orthodontic Bracket - Ceramic Model No.:NIL Intended Use:Orthodontic Brackets are known as dental braces in layman language. These are used for the purpose of straightening of crooked teeth. These are placed on the teeth and then they act as means of transferring forces of orthodontic wires to teeth. Once the treatment with braces is over, these are removed from the teeth and discarded Class of medical device:Class B Material of construction:Ceramic i.e. Polycrystalline aluminum oxide these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
3	Generic Name:Orthodontic Molar Tube Model No.:NIL Intended Use:Orthodontic Molar Tubes are technically brackets only. These are tube-like brackets which are used for the purpose of straightening of crooked molar teeth. These are placed on the molar teeth and then they act as means of transferring forces of orthodontic wires to molar teeth. Once the treatment with braces is over, these are removed from the molar teeth and discarded Class of medical device:Class B Material of construction:Stainless Steel 17-4 PH, Stainless Steel 316L,. All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
4	Generic Name:Orthodontic Molar Bands Model No.:NIL Intended Use:Orthodontic Molar Bands are ring like structures which embrace the tooth. These are used for the purpose on molar teeth where direct placement of Molar Tubes is not possible due to higher forces of mastication required during chewing which can dislodge the molar tubes if placed directly. So the molar bands are placed around the teeth and the molar tubes are welded on to the bands for providing greater strength to the molar tubes thereby preventing accidental dislodging of the tubes. Class of medical device:Class B Material of construction:Stainless Steel 305,. All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades. Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

5	Generic Name:Orthodontic Wires - Stainless Steel Model No.:NIL Intended Use:Orthodontic Wires are the means for exerting pressure on the teeth which results into the movement of teeth. Different wires are used during different stages of treatment. These wires vary both in size and cross section as well as the alloy. During the initial phases of treatment, thinner wires made of titanium alloys are used for application of lighter forces. Slowly, as the treatment progresses, these wires are replaced by more thicker and stronger stainless steel wires which provide a strong track on which the teeth can be moved Class of medical device:Class B Material of construction:Stainless Steel 304,. All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
6	Generic Name:Orthodontic Wires -Ni-Ti Model No.:NIL Intended Use:Orthodontic Wires are the means for exerting pressure on the teeth which results into the movement of teeth. Different wires are used during different stages of treatment. These wires vary both in size and cross section as well as the alloy. During the initial phases of treatment, thinner wires made of titanium alloys are used for application of lighter forces. Slowly, as the treatment progresses, these wires are replaced by more thicker and stronger stainless steel wires which provide a strong track on which the teeth can be moved. Class of medical device:Class B Material of construction:Medical grade NickelTitanium Alloy All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
7	Generic Name:Orthodontic Wires- Beta Titanium Model No.:NIL Intended Use:Orthodontic Wires are the means for exerting pressure on the teeth which results into the movement of teeth. Different wires are used during different stages of treatment. These wires vary both in size and cross section as well as the alloy. During the initial phases of treatment, thinner wires made of titanium alloys are used for application of lighter forces. Slowly, as the treatment progresses, these wires are replaced by more thicker and stronger stainless steel wires which provide a strong track on which the teeth can be moved Class of medical device:Class B Material of construction:Medical grade Beta Titanium Alloy All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades. Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

8	Generic Name:Orthodontic Elastomerics Model No.:NIL Intended Use:Orthodontic Elastomeric are basically of three types and are used like disposable force exerting units as and when required during orthodontic treatment. Elastomeric Chains, Elastics, Elastic Thread and Elastic Tubing help in exerting "pulling-forces" on a tooth or a group of teeth. Ties are used for holding orthodontic wire into the brackets. Separators help in creating desired distance between two adjacent teeth in facilitating the placement of orthodontic bands. Rotation Wedges help in de-rotating a rotated tooth. Class of medical device:Class B Material of construction:Elastomerics are made from Thermoplastic Polyurethane. These are available in various colours to enhance the aesthetics and patient acceptability. Thermoplastic Polyurethane time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades. Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL
9	Generic Name:Orthodontic Adhesives Model No.:NIL Intended Use:Orthodontic Adhesives help in fixation of Orthodontic Brackets, Tubes and Accessories on teeth. Firstly the tooth surface is prepared by polishing and applying etchant for a certain period of time. Etchant is used to create rough surface which helps in gaining sufficient adhesion strength. After this, primer is applied which goes into micro-defects created by etchant. It is then followed by application of adhesive which gets hardened either by contact with the primer or by a light source. Class of medical device:Class B Material of construction:Etchant is 36% ortho-phosphoric acid gel which is washed off . Adhesive consist of monomer i.e .Bis -GMA is a combination of binders and fillers in the form of paste which can be cured by reaction with primer or a light source All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades. Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

10	Generic Name:Orthodontic Acessories Model No.:NIL Intended Use:Orthodontic accessories are the devices which are used along-with main bracket-wire combination for the purposes as given below; Lingual Sheath helps in holding the trans-palatal arch bars which in turn helps in making two molars on opposite side as one anchorage unit. Lingual Buttons, Cleats, Lugs, Direct Bond Eyelets, Crimpable Hooks, Crimpable Ball Hooks and Crimpable Stops are used as means of applying the elastomerics and springs for movement of various teeth. Trans-palatal arch bars help in making two molars on opposite side as one anchorage unit so that they can offer better resistance to movement of front teeth. Class of medical device:Class B Material of construction:Stainless Steel 17-4 PH, Stainless Steel 316L , stainless steel 305,. All these types of materials are time-tested and proven to be used as Orthodontic Materials in Orthodontic Industry for decades Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

Place:

Date:03-Jun-21

State Licensing Authority

Joint Commissioner (Drugs)-cum-
Licensing Authority, Punjab,
Near Civil Hospital, Mohali-140301,
District Sahibzada Ajit Singh Nagar

सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2021/000155

Endorsement No. 1

1. M/s Modern Orthodontics, 2024, Gobind Nagar, Circuit House Road, Ludhiana, Ludhiana, Punjab (India) - 141001 Telephone No.: 7738993291 FAX: 01612412312 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Modern Orthodontic, Hambran Industrial Area, Mullanpur Road, Village Hambran, , Ludhiana, Punjab (India) - 141110 Telephone No.: 7738993291 FAX: 01612412312

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Orthodontic Wires- Stainless Steel Coated Model No.:NIL Intended Use:Orthodontic Wires are the means for exerting pressure on the teeth which results into the movement of teeth. Different wires are used during different stages of treatment. These wires vary both in size and cross section as well as the alloy. During the initial phases of treatment, thinner wires made of titanium alloys are used for application of lighter forces. Slowly, as the treatment progresses, these wires are replaced by more thicker and stronger Stainless Steel Coated wires which provide a strong track on which the teeth can be moved. Class of medical device:Class B Material of construction:Stainless Steel 304 and PTFE Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

2	Generic Name:Orthodontic Wires- Ni- Ti Coated Model No.:NIL Intended Use:Orthodontic Wires are the means for exerting pressure on the teeth which results into the movement of teeth. Different wires are used during different stages of treatment. These wires vary both in size and cross section as well as the alloy. During the initial phases of treatment, thinner wires made of titanium alloys are used for application of lighter forces. Slowly, as the treatment progresses, these wires are replaced by more thicker and stronger Stainless Steel Coated wires which provide a strong track on which the teeth can be moved. Class of medical device:Class B Material of construction:Nickel- Titanium alloy and PTFE Dimension(if any): Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):NIL

Place: Kharar

Date21-Mar-22

21/03/2022

State Licensing Authority
Joint Commissioner(Drugs)-cum-
Licensing Authority,
Food & Drugs Administration, Punjab,